EXPERTS' OPINIONS AND POSITION PAPERS

Rotational atherectomy in everyday clinical practice. Association of Cardiovascular Interventions of the Polish Society of Cardiology (*Asocjacja Interwencji Sercowo-Naczyniowych Polskiego Towarzystwa Kardiologicznego* — AISN PTK): Expert opinion

Sławomir Dobrzycki[1], Krzysztof Reczuch[2, 3], Jacek Legutko[4], Tomasz Pawłowski[5], Marek Grygier[6], Andrzej Ochała[7], Jarosław Wójcik[8], Paweł Buszman[9], Dariusz Dudek[10], Mariusz Gąsior[11], Robert Gil[5], Maciej Lesiak[6], Krzysztof Kukuła[12], Adam Witkowski[12], Wojciech Zajdel[4], Paweł Kralisz[1], Wojciech Wojakowski[13], Stanisław Bartuś[10]

[1]Department of Invasive Cardiology, Medical University in Bialystok, Bialystok, Poland
[2]Department of Heart Diseases, Medical University, Wroclaw, Poland
[3]Centre for Heart Diseases, 4th Military Clinical Hospital, Wroclaw, Poland
[4]Interventional Cardiology Department, Institute of Cardiology, Medical College of Jagiellonian University, Krakow, Poland
[5]Department of Invasive Cardiology, Central Clinical Hospital of the Ministry of Interior and Administration, Warsaw, Poland
[6]1st Department of Cardiology, Medical University, Poznan, Poland
[7]3rd Department of Cardiology, Silesian Medical University, Katowice, Poland
[8]Clinical Ward of Cardiology, Independent Public Clinical Hospital No. 4, Lublin, Poland
[9]Silesian Centre for Heart Diseases, Zabrze, Poland
[10]2nd Department of Cardiology, Institute of Cardiology, Medical College of Jagiellonian University, Krakow, Poland
[11]3rd Department and Clinical Ward of Cardiology, Silesian Medical University, Zabrze, Poland
[12]Department of Cardiology and Interventional Angiology, Institute of Cardiology, Warsaw, Poland
[13]3rd Department of Cardiology, Silesian Medical University, Katowice, Poland

Abstract

The common use of stents, including antiproliferative drug-eluting stents, has been a major breakthrough in invasive cardiology. Nowadays, a change in the clinical presentation of patients treated with percutaneous coronary intervention (PCI) is observed. The typical clinical characteristics now include advanced age, diabetes, chronic kidney disease, heart failure, and multilevel atherosclerosis. Age, diabetes, and chronic kidney disease are the main predictors of coronary artery calcifications. Severe coronary artery calcifications are the main factor limiting the efficacy of PCI. Successful stent implantation is challenging in the presence of calcifications, because it is difficult to achieve full stent expansion and proper stent apposition. Therefore, it is necessary to adequately prepare the lesion before stent implantation. This document presents the technique of rotational atherectomy (rotablation) as well as indications for and contraindications to the procedure, along with its possible complications and their prevention. Training in rotablation for operators as well as reimbursement policy for the procedure in Poland are also discussed.

Key words: rotational atherectomy, rotablation, percutaneous coronary angioplasty, coronary heart disease

Kardiol Pol 2018; 76, 11: 1576–1584

Address for correspondence:
Stanisław Bartuś, MD, PhD, 2nd Department of Cardiology, Institute of Cardiology, Jagiellonian University Medical College, ul. Kopernika 17, 31–501 Kraków, Poland, e-mail: stanislaw.bartus@uj.edu.pl

INTRODUCTION

Nowadays, patients undergoing percutaneous coronary interventions (PCIs) are quite different in terms of their clinical and angiographic characteristics than those subjected to PCIs in the past. Currently, the typical clinical features of these patients are advanced age, diabetes, chronic kidney disease, heart failure, and multilevel atherosclerosis [1, 2]. These factors contribute to the severity of atherosclerotic lesions as well as the procedural risk [3, 4]. According to current recommendations of cardiological societies, the final decision on the method of revascularisation in patients with stable ischaemic heart disease and complex coronary artery lesions (especially in the presence of left main stenosis and/or multivessel disease) should be made by a multidisciplinary team including a cardiac surgeon, an interventional cardiologist, and a cardiologist (Heart Team) [5].

Age, diabetes, and chronic kidney disease are the main predictors of coronary artery calcifications. Severe calcifications are the main factor limiting the efficacy of PCI procedures, both in terms of early and long-term outcomes [6, 7]. The common use of stents, including antiproliferative drug-eluting stents (DESs), has been a breakthrough in invasive cardiology. For a successful stent implantation, it is essential to achieve full stent expansion and its proper adhesion to the vascular wall (apposition). The presence of calcifications makes stent implantation difficult or even impossible, so adequate preparation of the lesion before the procedure is necessary. Inadequate apposition increases the risk of in-stent thrombosis and restenosis.

ROTATIONAL ATHERECTOMY (ROTABLATION)

Rotational atherectomy (RA), which was introduced into clinical practice in 1988, is the most effective method of calcified plaque modification [7–9]. RA, also known as rotablation, extends the coronary artery lumen by removing part of the atheromatous plaque and its softening, thus facilitating vessel dilatation. The plaque is removed by breaking it into microparticles of < 10 μm in size (approximately 5 μm on average), which enables their free passage through the coronary microcirculation. First, a metal guidewire with a diameter of 0.009 inches is introduced into the distal bed of the target vessel. Then, a diamond-coated elliptical burr at the tip of a flexible drive shaft is advanced coaxially over the guidewire. The burr, rotating at a speed of 130,000–180,000 rpm, ablates more than 98% of the plaque into the microparticles. The burr is driven by an air turbine using compressed gas to generate the high rotational speed [8–10]. The device components include gas supply with compressed air or nitrogen (> 6 atm), which is connected to the control console, air turbine, and foot pedal activating the drive. The disposable parts include the burr and the 0.009-inch steel guidewire (with a 0.014-inch tip) connected to the advancer. The tip is thicker to allow a removal of the burr together with the guidewire in case of damage. The burr is placed in a special sheath that enables a continuous administration of normal saline and various drugs to the site of ablation. The device is produced by Boston Scientific, the only manufacturer of such devices until 2007. In 2007, a system for so called orbital atherectomy (Orbital Atherectomy System, Cardiovascular System, Inc., St. Paul, MN, USA) was developed, which works in a similar way but has a slightly different ablation element, also covered with a diamond crown. The system is set in a rotational motion with a pneumatic or an electric drive. Its working speed is between 80,000 and 120,000 rpm. The first published results for the use of this system are promising [11, 12].

ROTATIONAL ATHERECTOMY PROCEDURE PROTOCOL AND PERIPROCEDURAL PHARMACOTHERAPY

Patients undergoing RA should be prepared in the same way as any other patient undergoing a PCI procedure. Dual antiplatelet therapy should be administered early enough to inhibit platelet function [5]. Before the procedure, use of sedative drugs and preparation of vascular access are advisable. As most patients referred for RA are at older age and have multiple comorbidities, including diabetes and chronic kidney disease, it is important to maintain normal glucose levels in the periprocedural period and prevent contrast-induced nephropathy [13].

VASCULAR ACCESS AND GUIDEWIRES

The choice of a vascular access depends on the experience of the centre and the burr size. Standard burr sizes are 1.25, 1.5, and 1.75 mm, and they are compatible with 6 Fr (French) guiding catheters. There is basically no need to use guiding catheters greater than 7 Fr because the burrs over 2 mm are rarely used, which enables the use of a radial access in the majority of RA procedures. Coaxial positioning of the guiding catheter in the coronary artery ostium is essential for the RA procedure itself and its subsequent stages. An interesting modification of the radial access is the use of sheathless guiding catheters, which have a greater internal diameter while causing less damage to the vessel. An additional advantage is their hydrophilicity, which facilitates their advancement even through a narrow radial artery. However, these guiding catheters have a weak support, which may limit stent delivery [14, 15]. Another option is the use of a thin-walled sheath dedicated for radial-access procedures, which enables the use of a standard guiding catheter with a one-size greater diameter (i.e. for the 6-Fr sheath, the 7-Fr guiding catheter can be used).

The RA procedure requires the use of dedicated guidewires of 330 cm in length, which come in two types depending on their stiffness (Floppy and Extra Support). Their introduction to the distal segment of the artery is much more difficult than with a standard PCI guidewire. To solve this problem, microcatheters or over-the-wire balloon catheters are used, which allow a replacement of a standard guidewire for PCI with a guidewire for RA. Next, a suitable burr size has to be selected and advanced to the target lesion. Current guidelines and leading centres recommend plaque modification, which involves the use of a single burr with a size of < 0.7 of the vessel diameter [9, 10]. Plaque modification is associated with a lower complication rate than the previously used plaque debulking technique aimed at removing the highest possible volume of the atheromatous plaque [16, 17]. However, the increasingly common strategy is to use the smallest possible burr size (1.25 mm) to incise the atheromatous plaque, which is believed to reduce the risk of complications. This technique is usually effective because the target vessels are narrow and severely calcified along their entire length. The rotational speed should range between 130,000 and 180,000 rpm, and it is recommended to advance the burr in a smooth pecking motion, with a duration of an individual burr run between 10 and 30 s. The burr should be retreated from the lesion at the end of each cycle to avoid its entrapment. The speed of the burr should be monitored at all times, and in the case of deceleration > 5000 rpm, the pressure on the lesion should be reduced, the burr should be retreated from the lesion, and the individual burr run should be stopped if needed [9, 17]. During rotablation, thermal energy is produced, which increases the temperature in the lesion by several Celsius degrees. Long run times with a considerable reduction of rotational speed (by several thousand rpm) result in a local increase in the temperature even by more than 10°C [18, 19]. In case of resistance in the lesion, the speed can be increased up to 180,000–200,000 rpm, with a simultaneous reduction in individual time runs to avoid generating too much heat. Moreover, high speed increases platelet activation. Both these effects contribute to periprocedural myocardial necrosis [19, 20]. Ablation of tortuous lesions should be performed at lower burr speed (100,000–120,000 rpm) and sizes, which reduces the risk of vessel perforation [21]. An important component of the procedure is the use of rotablation flushing cocktail. Its composition varies, but it always includes heparin, nitroglycerin, verapamil or other drugs from this class, or nicorandil [22]. The cocktail infusion reduces the risk of slow-flow/no-reflow phenomena and the rate of periprocedural myocardial infarction (MI) [23, 24]. Another way to reduce blood flow disturbances during RA is intravenous administration of glycoprotein IIb/IIIa platelet receptor antagonists. The most thoroughly investigated drug of this class is abciximab [25]. Currently, this drug class is reserved mainly for bail-out use after evaluation of individual risk of haemorrhagic and ischaemic complications. The available data indicate that the use of bivalirudin, a direct thrombin inhibitor, does not offer a clinical benefit in comparison with a routinely used unfractionated heparin [26].

After a successful rotablation the course of the procedure is similar to that in other complex PCIs. The subsequent stages are performed using classic extra-support guidewires for PCI, which are advanced parallel to the RA guidewire or they are introduced to replace the RA guidewire using a microcatheter or over-the-wire balloon. Before stent deployment, the rotablation guidewire should be retracted to avoid its entrapment in the vessel. Balloon post-dilatations are performed using non-compliant balloons or balloon catheters designed for very high pressures (even above 30 atm). In the case of a resistant lesion, another ablation with a larger-sized burr can be considered. The one-burr approach is also economically reasonable, especially in countries where the RA procedure alone is not reimbursed or the reimbursement is insufficient (in Poland, there had been no reimbursement until 1 January 2017, and since 1 January 2017, there has been partial reimbursement). There is much controversy over the management algorithm after successful passage with the first burr due to a lack of scientific evidence. According to a European expert consensus on RA, in the case of low-pressure-inflated balloon or incomplete balloon expansion, rotablation should be continued with a larger-sized burr [10]. This consensus resulted from a compromise between two expert groups with opposing views. The first group considered the use of another larger-sized burr to be the safest strategy, while the other stated that high-pressure inflations with or without cutting balloons are sufficient in most cases. However, high-pressure inflation may be insufficient and may cause dissection, which represents a contraindication to further rotablation. It is thus possible to use scoring and cutting balloons, which are currently not reimbursed in Poland [9, 21, 27]. The final stage of a PCI with RA is stent implantation. Because of severe calcifications and long lesions, stent delivery is often difficult. For the subsequent RA stages to be successful, it is important to use a suitable guiding catheter and pay attention to its coaxial positioning in the coronary artery ostium. Moreover, the shape of the catheter should be adjusted to the target vessel. In case of any difficulties in stent delivery, the use of a "mother-and-child" technique is recommended [28].

Another issue is temporary pacing during RA. During the procedure, a neurohumoral response is induced, which leads to bradycardia [8, 29]. When RA was introduced into clinical practice, temporary pacing was obligatory during all RA interventions. However, the increasing experience of teams performing rotablation and a comprehensive assessment of procedure outcomes, including periprocedural complications, have led to a change in the approach. Despite the lack of uniform recommendations, it seems reasonable to state that preventive pacing is not necessary. In case of bradycardia during the procedure, the use of atropine and pacing are recommended [9, 21, 29]. This statement is based on the results of two large studies published in 2012 and 2014 [30, 31]. The analyses included over 5000 patients treated with RA. In a British registry [31], which analysed the outcomes of RA in 2152 patients, temporary pacing was necessary in as few as 1.3% of individuals, as compared with 0.3% in patients undergoing PCI without RA. In our opinion, preventive implantation of a temporary pacing electrode can be justified only in cases when RA is performed in a dominant right coronary artery with long lesions.

The Expert Group of the Association of Cardiovascular Interventions of the Polish Society of Cardiology (*Asocjacja Interwencji Sercowo-Naczyniowych Polskiego Towarzystwa Kardiologicznego* — AISN PTK) recommends performing RA according to proposed protocols for patient preparation as well as for the selection of a vascular access, guiding catheter, and burr size. During the procedure, it is important to apply short burr run times, monitor the rotational speed, and use rotablator flushing cocktail. The procedure should be started at a lower rotational speed, and, if ineffective, it should be increased and/or the smallest-sized burr should be used. Strict compliance with these recommendations will prevent or reduce complications.

INDICATIONS FOR AND CONTRAINDICATIONS TO ROTATIONAL ATHERECTOMY. PREVENTION OF COMPLICATIONS

Stent implantation in a lesion that is resistant to balloon dilatation is contraindicated and will not result in vessel dilatation. RA procedures are performed most often after a previous PCI failure due to inability to cross the lesion with the smallest balloon or adequately dilate the lesion with a high-pressure balloon (> 16 atm). The use of very high pressure increases the risk of vessel perforation, while rescue delivery of a stent graft to a long calcified lesion may be impossible. This indication for rotablation has a IC class of recommendation in the 2010 European Society of Cardiology and European Association for Cardio-Thoracic Surgery guidelines on cardiac revascularisation [32]. In these indications, rotablation is the only effective percutaneous treatment. Rotablation in mild or moderate coronary artery calcifications does not provide satisfactory outcomes and is associated with an increased risk of complications [9, 21]. Therefore, it is crucial to evaluate the degree of calcifications before considering patients for RA. Severe calcifications are diagnosed when they can be identified on an angiographic image before contrast administration into the artery lumen, and they usually involve both walls of the vessel. Moderate calcifications are visible only during the cardiac cycle on coronary angiography. Computed tomography (CT), intravascular ultrasound (IVUS), and optical coherence tomography (OCT) can provide much more information on the localisation and severity of coronary artery calcifications [10, 33–35]. Tomey et al. [9] proposed an algorithm for the use of RA in clinical practice. Severe calcifications on coronary angiography are an indication for RA. If calcification is moderate or cannot be determined by angiography, additional testing with IVUS or OCT is recommended. IVUS allows a precise assessment of the site of calcification (superficial, localised between the vessel lumen and media, versus deep, localised between the vascular media and adventitia) and the measurement of the calcium arc. OCT additionally allows a precise quantitative evaluation of calcium layer thickness. Data obtained with IVUS and OCT may facilitate the planning of a PCI procedure or may modify its course, but RA is beneficial mainly in patients with superficial calcifications involving > 227° of the vessel wall circumference and > 0.67-mm thickness on OCT [36, 37]. Indications for rotablation are presented in Table 1.

Rotational atherectomy facilitates a successful PCI procedure in the case of complex lesions (type B2 and C according to the American Heart Association/American College of Cardiology classification), including chronic total occlusions, ostial lesions, and bifurcations [38–42]. The ROSTER study [43] showed a beneficial effect of RA followed by adjunctive balloon dilatation at low pressure in the treatment of in-stent restenosis in comparison with high-pressure balloon angioplasty. On the other hand, the ARTIST study [44] revealed unfavourable outcomes of in-stent restenosis treatment with RA. RA significantly increased the rates of restenosis. These discrepancies may result from using different inclusion criteria and different definitions of restenosis. Optimal treatment outcomes in these indications may be achieved by using IVUS-guided PCI. Other rare indications for using RA include inadequate expansion of a metal stent or bioresorbable scaffold (stent ablation and scaffold ablation) [45, 46]. Contraindications to RA are presented in Table 2.

Although vein graft stenosis is an absolute contraindication to RA, ostial stenosis after aortic or coronary artery bypass grafting may be an exception. In literature reports, the use of RA in patients with acute coronary syndromes (including ST-segment elevation MI) were involved vessels with a different degree of thrombus burden. For example, in an Italian registry, 37% of the 1308 included patients underwent RA due to acute coronary syndromes [47]. Of course, the use of RA in these indications is often forced by PCI failure. PCI failure can also justify the use of RA in case of vessel dissection. In the presence of relative contraindications, RA procedures are performed more often and typically in cases when the patient does not consent to cardiac surgery or the surgical risk is too high. In selected high-risk patients with severe left ventricular dysfunction, mechanical circulatory support is a feasible option. The PROTECT II study [48] evaluated the use of intra-aortic counterpulsation and an Impella heart pump. Before deciding on the use of rotablation in these indications, a higher risk of severe complications should be considered and the patient's consent should be obtained. Moreover, the eligibility of a patient to undergo these procedures should be assessed by a local Heart Team.

Possible complications of RA, as well as their prevention and management, are listed in Table 3.

The Expert Group of the AISN PTK recommends RA in patients with refractory lesions that cannot be crossed or dilated with a balloon due to severe calcifications or

Table 1. Indications for rotational atherectomy

Classic indications	Calcified or fibrotic stenosis that cannot be adequately dilated with a balloon
	Lesions that cannot be crossed with a balloon
Additional indications	Severe calcifications on angiography, intravascular ultrasonography, and/or optical coherence tomography if there is a risk of balloon angioplasty or stent implantation failure
	Severely calcified bifurcation lesions, including left main bifurcation
	Chronic total occlusion (CTO) recanalisation after successful CTO crossing
Off-label indications	Ablation of underexpanded stents or bioresorbable vascular scaffolds

Table 2. Contraindications to rotablation

Absolute contraindications*	Relative contraindications
Vein graft lesions	Severe left ventricular dysfunction (ejection fraction < 30%)
Thrombus	Severe three-vessel disease
Angiographic signs of vessel dissection	Severe unprotected left main stenosis
	Lesions of > 25 mm in length
	Lesions of > 45 degrees in tortuous segments

*Rotablation is possible if other methods are ineffective

Table 3. Complications specific to rotablation procedures and preventive measures. Complications common for all types of percutaneous coronary interventions were not listed

Complication	Preventive measures
Blood flow disturbances in the target vessel (slow flow/no reflow) Angina pectoris Myocardial infarction	Short duration of individual burr runs (10–20 s) Smaller burr size Reduced rotational speed Minimising decelerations during rotablation Use of flushing cocktail Glycoprotein IIb/IIIa receptor antagonists Adenosine
Vessel perforation	Plaque modification Smaller burr size Reduced rotational speed in tortuous segments Larger size of the subsequent burr (by 0.25–0.5 mm) Prolonged balloon inflation Stent-graft implantation Cardiac surgery
Bradycardia, cardiac block	Atropine, provisional temporary pacing Preventive use of atropine before crossing the lesion Preventive implantation of an intraventricular electrode in selected patients
Burr entrapment	Short duration of individual burr runs Minimising decelerations during rotablation Retraction of the burr from the lesion between individual burr runs Balloon inflation proximal to burr entrapment to retrieve a stuck rotablator burr Use of the "mother-and-child" technique, deep-vessel intubation with a guiding catheter (e.g. GuideLiner) Cardiac surgery
Guidewire tip detachment	Do not advance the burr to the distal end of the guidewire Attempt removal with a loop snare Stent implantation at the site of detachment

fibrosis. RA should be considered as primary treatment in patients with severely calcified lesions. Centres without access to RA should refer their patients to selected reference centres.

The Expert Group of the AISN PTK does not recommend RA in thrombotic lesions, vein grafts, or in the presence of vessel dissection. If other relative contraindications are present (ejection fraction < 30%, multivessel coronary artery disease, trunk stenosis), RA should be performed only in experienced centres with cardiac surgical facilities.

EFFICACY OF ROTATIONAL ATHEROTECTOMY: RESULTS OF CLINICAL TRIALS

Rotational atherectomy was introduced into clinical practice as an alternative option to standard balloon angioplasty. Early studies reported that RA had similar efficacy to percutaneous transluminal coronary angioplasty and other transcatheter interventions [49–51]. The procedure was soon proved to be useful in the treatment of patients with PCI failure, mainly those with long and severely calcified lesions [52, 53]. The ERBAC study [54], one of the important randomised trials evaluating different coronary interventions, compared RA with excimer laser angioplasty and conventional balloon angioplasty. Patients who underwent RA had a higher procedural success rate and a significantly lower rate of composite endpoint (death, MI, or need for coronary artery bypass grafting) than those who underwent excimer laser angioplasty or conventional balloon angioplasty. In all groups restenosis rates were unacceptably high (> 50%). Hoffmann et al. [55] reported that the use of RA followed by stent implantation resulted in a significant improvement in early and long-term outcomes in comparison with PCI or stent implantation alone without RA in patients with long calcified lesions. The STRATAS [56] and CARAT [57] trials showed that RA does not provide better long-term angioplasty outcomes. The studies were important in that they showed that aggressive burr sizing (burr/artery ratio > 0.7) was associated with a significantly higher rate of perioperative complications. This aggressive strategy was aimed at reducing the plaque volume (plaque debulking). The results of those trials raised controversy around RA and led to the search for new strategies. As a consequence, a technique known as plaque modification was developed, in which smaller-sized burrs were used. When combined with the introduction of DESs, the method again found its way into clinical practice to be used in selected populations.

Numerous studies showed DES to be superior to bare metal stent implantation following RA procedures. DES implantation after rotablation is known as Rota-DES technique [58, 59]. In a large registry evaluating the results of Rota-DES in over 200 patients during a nine-month follow-up, Abdel-Wahab et al. [60] reported the cumulative incidence of major adverse cardiac events of 17.7% (death, 4.4%; MI, 3.4%; target vessel revascularisation, 9.9%; and target lesion revascularisation, 6.8%). Only two incidents of late in-stent thrombosis (one definite and one probable) occurred. The authors concluded that the results were very promising in this patient population. The randomised ROTAXUS trial [61] compared two strategies of DES implantation in calcified coronary artery lesions: with previous RA and with high-pressure balloon predilatation. Patients who did not undergo RA had worse outcomes and required a crossover into the RA group. The authors concluded that standard balloon predilatation is the method of choice in calcified lesions, with the use of RA in case of failure.

According to the Polish registry of invasive cardiology procedures (*Ogólnopolski Rejestr Procedur Kardiologii Inwazyjnej* — ORPKI), RA is widely available, mainly due to reimbursement, and the number of procedures has increased each year due to population aging [62]. The number of periprocedural complications is higher for RA than for standard coronary angioplasty, but patients undergoing RA are generally at high operative risk [62, 63]. Moreover, according to Polish data, the use of RA in patients with acute coronary syndrome, including MI, does not increase the operative risk or worsen angiographic outcome [64, 65]. However, the patient's prognosis depends not only on classic risk factors, such as heart failure, but also on whether they underwent complete revascularisation [63, 65].

ROTATIONAL ATHERECTOMY: TRAINING SYSTEM FOR OPERATORS

Rotational atherectomy is one of the most difficult and challenging procedures in interventional cardiology and is associated with an increased risk of complications due to complexity of the procedure alone, complexity of coronary artery lesions, as well as the complex clinical condition of patients treated with RA. Therefore, the requirements for operators and invasive cardiology centres should be much higher. In our opinion, RA procedures should be performed in catheterisation laboratories of a high referential level (B and C in Poland according to the AISN PTK) by independent invasive cardiologists fulfilling AISN PTK criteria, who have performed independently at least 500 PCI procedures [66]. When the method is implemented in a new centre, the first procedures should be performed under supervision of an experienced operator.

The Expert Group of the AISN PTK recommends introducing a graded RA training programme for operators. The procedure can be performed by a qualified invasive cardiologist who has obtained the AISN PTK certificate of an independent operator and who has performed at least 500 procedures of coronary angioplasty. After completing theoretical and practical training (workshops, manufacturer trainings), it is recommended that the operator should perform at least 10 RA procedures (as the first or second operator) under supervision of an experienced operator.

It is recommended that RA procedures are performed by at least two certified doctors.

REIMBURSEMENT OF ROTATIONAL ATHERECTOMY PROCEDURE IN POLAND

At the request of the Board of the AISN PTK and the National Consultant of Cardiology, since 1 January 2017 the medical procedure "Coronary atherectomy — rotablation" has been included in the list of health care services available for reimbursement (number 5.53.01.0005004 in attachment 1c to the Regulation No. 38/2017/DSOZ of the President of the Polish National Health Fund of 29 May 2017) [67, 68]. The reimbursement of rotablation may be grouped with all types of PCI procedures, both in acute coronary syndromes and stable coronary artery disease, as well as with IVUS or fractional flow reserve assessment. The procedure can be reimbursed on condition that it is assigned an ICD-9 00.662 code for coronary atherectomy and one of the two following clinical indications are present: 1) severely calcified atheromatous lesions in the coronary artery, both in the native artery and in the neointima in patients with in-stent restenosis, that cannot be crossed or dilated with a balloon; or 2) severely calcified lesions on coronary angiography, IVUS, or OCT that do not allow adequate stent expansion [69].

The Expert Group of AISN PTK recommends that angiographic images of RA performed during PCI are registered and archived and that clinical indications for RA and its reimbursement are noted in the patient's medical records.

SUMMARY

The literature review of the history of RA since its introduction into clinical practice confirms its usefulness in facilitating PCIs for the treatment of calcifications of complex atherosclerotic lesions. Growing experience in the use of RA, a better understanding of plaque modification mechanisms, and the utilisation of the most experienced catheterisation laboratories have minimised the rate of complications. The new system of training in RA, which involves the selection of reference centres and a supervision of this difficult procedure at early stages of implementation, will improve outcomes, and in particular, will reduce complication rates. Further studies are needed to evaluate the effects of combining different plaque modification techniques including RA as well as high-pressure, cutting, and scoring balloons on improvement of early and long-term outcomes. Research is also needed to assess another technique for high-speed rotablation, namely orbital atherectomy, which was introduced into clinical practice a few years ago and has already shown some promising results. It is still unclear whether patients can be considered for RA on the basis of angiography results only. Selection for RA only of patients with PCI failure seems to be limiting the subset of patients who might benefit from this treatment. Using additional criteria for patient selection on the basis of IVUS, OCT, and CT may help identify individuals in whom RA will be the most beneficial.

Conflict of interest: *Sławomir Dobrzycki, Paweł Kralisz, Krzysztof Reczuch — proctorship agreement for rotablation and speakers fee: Boston Scientific Poland. Other authors declare no conflict of interest.*

References

1. Tsai TT, Patel UD, Chang TI, et al. Contemporary incidence, predictors, and outcomes of acute kidney injury in patients undergoing percutaneous coronary interventions: insights from the NCDR Cath-PCI registry. JACC Cardiovasc Interv. 2014; 7(1): 1–9, doi: 10.1016/j.jcin.2013.06.016, indexed in Pubmed: 24456715.
2. Malyszko J, Bachorzewska-Gajewska H, Malyszko JS, et al. Prevalence of chronic kidney disease in elderly patients with normal serum creatinine levels undergoing percutaneous coronary interventions. Gerontology. 2010; 56(1): 51–54, doi: 10.1159/000265560, indexed in Pubmed: 19996581.
3. Sianos G, Morel MA, Kappetein AP, et al. The SYNTAX Score: an angiographic tool grading the complexity of coronary artery disease. EuroIntervention. 2005; 1(2): 219–227, indexed in Pubmed: 19758907.
4. Chang-Wook Nam , Mangiacapra F, Entjes R, et al. Functional SYNTAX score for risk assessment in multivessel coronary artery disease. J Am Coll Cardiol. 2011; 58(12): 1211–1218, doi: 10.1016/j.jacc.2011.06.020, indexed in Pubmed: 21903052.
5. Windecker S, Kolh P, Alfonso F, et al. 2014 ESC/EACTS guidelines on myocardial revascularization. EuroIntervention. 2015; 10(9): 1024–1094, doi: 10.4244/EIJY14M09_01, indexed in Pubmed: 25187201.
6. Stavroulopoulos A, Porter CJ, Pointon K, et al. Evolution of coronary artery calcification in patients with chronic kidney disease Stages 3 and 4, with and without diabetes. Nephrol Dial Transplant. 2011; 26(8): 2582–2589, doi: 10.1093/ndt/gfq751, indexed in Pubmed: 21224493.
7. Madhavan MV, Tarigopula M, Mintz GS, et al. Coronary artery calcification: pathogenesis and prognostic implications. J Am Coll Cardiol. 2014; 63(17): 1703–1714, doi: 10.1016/j.jacc.2014.01.017, indexed in Pubmed: 24530667.
8. Ritchie JL, Hansen DD, Intlekofer MJ, et al. Rotational approaches to atherectomy and thrombectomy. Z Kardiol. 1987; 76 Suppl 6: 59–65, indexed in Pubmed: 3439260.
9. Tomey MI, Kini AS, Sharma SK. Current status of rotational atherectomy. JACC Cardiovasc Interv. 2014; 7(4): 345–353, doi: 10.1016/j.jcin.2013.12.196, indexed in Pubmed: 24630879.
10. Barbato E, Carrié D, Dardas P, et al. European expert consensus on rotational atherectomy. EuroIntervention. 2015; 11(1): 30–36, doi: 10.4244/EIJV11I1A6, indexed in Pubmed: 25982648.
11. Bhatt P, Parikh P, Patel A, et al. Orbital atherectomy system in treating calcified coronary lesions: 3-Year follow-up in first human use study (ORBIT I trial). Cardiovasc Revasc Med. 2014; 15(4): 204–208, doi: 10.1016/j.carrev.2014.03.004, indexed in Pubmed: 24746600.
12. Chambers JW, Feldman RL, Himmelstein SI, et al. Pivotal trial to evaluate the safety and efficacy of the orbital atherectomy system in treating de novo, severely calcified coronary lesions (ORBIT II). JACC Cardiovasc Interv. 2014; 7(5): 510–518, doi: 10.1016/j.jcin.2014.01.158, indexed in Pubmed: 24852804.
13. Bachorzewska-Gajewska H, Malyszko J, Sitniewska E, et al. NGAL (neutrophil gelatinase-associated lipocalin) and cystatin C: are they good predictors of contrast nephropathy after percutaneous coronary interventions in patients with stable angina and normal serum creatinine? Int J Cardiol. 2008; 127(2): 290–291, doi: 10.1016/j.ijcard.2007.04.048, indexed in Pubmed: 17566573.

14. Watt J, Oldroyd KG. Radial versus femoral approach for high-speed rotational atherectomy. Catheter Cardiovasc Interv. 2009; 74(4): 550–554, doi: 10.1002/ccd.22066, indexed in Pubmed: 19434605.
15. Kassimis G, Patel N, Kharbanda RK, et al. High-speed rotational atherectomy using the radial artery approach and a sheathless guide: a single-centre comparison with the. EuroIntervention. 2014; 10(6): 694–699, doi: 10.4244/EIJV10I6A121, indexed in Pubmed: 24425306.
16. Kobayashi Y, Gregorio JDe, Kobayashi N, et al. Lower restenosis rate with stenting following aggressive versus less aggressive rotational atherectomy. Catheter Cardiovasc Interv. 1999; 46(4): 406–414, doi: 10.1002/(sici)1522-726x(199904)46:4<406::aid-ccd4>3.0.co;2-z, indexed in Pubmed: 10216004.
17. Whitlow PL, Bass TA, Kipperman RM, et al. Results of the study to determine rotablator and transluminal angioplasty strategy (STRATAS). Am J Cardiol. 2001; 87(6): 699–705, indexed in Pubmed: 11249886.
18. Reisman M, Shuman BJ, Harms V. Analysis of heat generation during rotational atherectomy using different operational techniques. Cathet Cardiovasc Diagn. 1998; 44(4): 453–455, indexed in Pubmed: 9716217.
19. Reisman M, Shuman BJ, Dillard D, et al. Analysis of low-speed rotational atherectomy for the reduction of platelet aggregation. Cathet Cardiovasc Diagn. 1998; 45(2): 208–214, indexed in Pubmed: 9786404.
20. Williams MS, Coller BS, Väänänen HJ, et al. Activation of platelets in platelet-rich plasma by rotablation is speed-dependent and can be inhibited by abciximab (c7E3 Fab; ReoPro). Circulation. 1998; 98(8): 742–748, indexed in Pubmed: 9727543.
21. Saland KE, Cigarroa JE, Lange RA, et al. Rotational atherectomy. Cardiol Rev. 2000; 8(3): 174–179, indexed in Pubmed: 11174891.
22. Tsubokawa A, Ueda K, Sakamoto H, et al. Effect of intracoronary nicorandil administration on preventing no-reflow/slow flow phenomenon during rotational atherectomy. Circ J. 2002; 66(12): 1119–1123, indexed in Pubmed: 12499617.
23. Matsuo H, Watanabe S, Watanabe T, et al. Prevention of no-reflow/slow-flow phenomenon during rotational atherectomy: a prospective randomized study comparing intracoronary continuous infusion of verapamil and nicorandil. Am Heart J. 2007; 154(5): 994.e1–994.e6, doi: 10.1016/j.ahj.2007.07.036, indexed in Pubmed: 17967610.
24. Fischell TA, Haller S, Pulukurthy S, et al. Nicardipine and adenosine. Cardiovasc Revasc Med. 2008; 9(4): 224–228, doi: 10.1016/j.carrev.2008.03.002, indexed in Pubmed: 18928946.
25. Kini A, Reich D, Marmur JD, et al. Reduction in periprocedural enzyme elevation by abciximab after rotational atherectomy of type B2 lesions: Results of the Rota ReoPro randomized trial. Am Heart J. 2001; 142(6): 965–969, doi: 10.1067/mhj.2001.119382, indexed in Pubmed: 11717598.
26. Delhaye C, Wakabayashi K, Maluenda G, et al. Safety and efficacy of bivalirudin for percutaneous coronary intervention with rotational atherectomy. J Interv Cardiol. 2010; 23(3): 223–229, doi: 10.1111/j.1540-8183.2010.00546.x, indexed in Pubmed: 20636842.
27. Furuichi S, Tobaru T, Asano R, et al. Rotational atherectomy followed by cutting-balloon plaque modification for drug-eluting stent implantation in calcified coronary lesions. J Invasive Cardiol. 2012; 24(5): 191–195, indexed in Pubmed: 22562910.
28. Pershad A, Sein V, Laufer N. GuideLiner catheter facilitated PCI: a novel device with multiple applications. J Invasive Cardiol. 2011; 23(11): E254–E259, indexed in Pubmed: 22045089.
29. Jain D, Schäfer U, Dendorfer A, et al. Neurohumoral activation in percutaneous coronary interventions: apropos of ten vasoactive substances during and immediately following coronary rotastenting. Indian Heart J. 2001; 53(3): 301–307, indexed in Pubmed: 11516028.
30. Wasiak J, Law J, Watson P, et al. Percutaneous transluminal rotational atherectomy for coronary artery disease. Cochrane Database Syst Rev. 2012; 12: CD003334, doi: 10.1002/14651858.CD003334.pub2, indexed in Pubmed: 23235596.
31. Cockburn J, Hildick-Smith D, Cotton J, et al. Contemporary clinical outcomes of patients treated with or without rotational coronary atherectomy--an analysis of the UK central cardiac audit database. Int J Cardiol. 2014; 170(3): 381–387, doi: 10.1016/j.ijcard.2013.11.018, indexed in Pubmed: 24289876.
32. Wijns W, Kolh P, Danchin N, et al. Guidelines on myocardial revascularization: The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). European Association for Percutaneous Cardiovascular Interventions. Eur Heart J. 2010; 31: 2501–2555, doi: 10.1093/eurheartj/ehu278.
33. Moussa I, Ellis SG, Jones M, et al. Impact of coronary culprit lesion calcium in patients undergoing paclitaxel-eluting stent implantation (a TAXUS-IV sub study). Am J Cardiol. 2005; 96(9): 1242–1247, doi: 10.1016/j.amjcard.2005.06.064, indexed in Pubmed: 16253590.
34. Mintz G, Pichard A, Popma J, et al. Determinants and correlates of target lesion calcium in coronary artery disease: a clinical, angiographic and intravascular ultrasound study. J Am Coll Cardiol. 1997; 29(2): 268–274, doi: 10.1016/s0735-1097(96)00479-2.
35. Mehanna E, Bezerra HG, Prabhu D, et al. Volumetric characterization of human coronary calcification by frequency-domain optical coherence tomography. Circ J. 2013; 77(9): 2334–2340, indexed in Pubmed: 23782524.
36. Maejima N, Hibi K, Saka K, et al. Relationship between thickness of calcium on optical coherence tomography and crack formation after balloon dilatation in calcified plaque requiring rotational atherectomy. Circ J. 2016; 80(6): 1413–1419, doi: 10.1253/circj.CJ-15-1059, indexed in Pubmed: 27087360.
37. Lee MS, Shah N. The impact and pathophysiologic consequences of coronary artery calcium deposition in percutaneous coronary interventions. J Invasive Cardiol. 2016; 28(4): 160–167, indexed in Pubmed: 26301561.
38. Levin T, Holloway S, Feldman† T. Acute and late clinical outcome after rotational atherectomy for complex coronary disease. Cathet Cardiovasc Diagn. 1998; 45(2): 122–130, doi: 10.1002/(sici)1097-0304(199810)45:2<122::aid-ccd5>3.0.co;2-e, indexed in Pubmed: 9786388.
39. Reifart N, Vandormael M, Krajcar M, et al. Randomized comparison of angioplasty of complex coronary lesions at a single center. Excimer Laser, Rotational Atherectomy, and Balloon Angioplasty Comparison (ERBAC) Study. Circulation. 1997; 96(1): 91–98, indexed in Pubmed: 9236422.
40. Tsuchikane E, Suzuki T, Asakura Y, et al. Debulking of chronic coronary total occlusions with rotational or directional atherectomy before stenting: Final results of DOCTORS study. Int J Cardiol. 2008; 125(3): 397–403, doi: 10.1016/j.ijcard.2007.07.117, indexed in Pubmed: 18023899.
41. Tsuchikane E, Aizawa T, Tamai H, et al. Pre-drug-eluting stent debulking of bifurcated coronary lesions. J Am Coll Cardiol. 2007; 50(20): 1941–1945, doi: 10.1016/j.jacc.2007.07.066, indexed in Pubmed: 17996557.
42. Nageh T, Kulkarni NM, Thomas MR. High-speed rotational atherectomy in the treatment of bifurcation-type coronary lesions. Cardiology. 2001; 95(4): 198–205, doi: 10.1159/000047372, indexed in Pubmed: 11585995.
43. Sharma SK, Kini A, Mehran R, et al. Randomized trial of Rotational Atherectomy Versus Balloon Angioplasty for Diffuse In-stent Restenosis (ROSTER). Am Heart J. 2004; 147(1): 16–22, indexed in Pubmed: 14691413.
44. vom Dahl J, Dietz U, Haager PK, et al. Rotational atherectomy does not reduce recurrent in-stent restenosis: results of the angioplasty

versus rotational atherectomy for treatment of diffuse in-stent restenosis trial (ARTIST). Circulation. 2002; 105(5): 583–588, indexed in Pubmed: 11827923.
45. Lee S, Park KW, Kim HS. Stentablation of an underexpanded stent in a heavily calcified lesion using rotational atherectomy. J Cardiovasc Med (Hagerstown). 2012; 13(4): 284–288, doi: 10.2459/JCM.0b013e328339d924, indexed in Pubmed: 20489653.
46. Wagner S, Hünlich M, Hasenfuß G, et al. Successful ablation of a bioresorbable polymeric vascular scaffold by rotational atherectomy. Clin Res Cardiol. 2014; 103(6): 501–504, doi: 10.1007/s00392-014-0689-z, indexed in Pubmed: 24590003.
47. Boasi V, Piazza F, Boccuzzi G, et al. Clinical outcome of rotational atherectomy in complex calcified coronary lesions: data from the multicenter international ROTATE registry. EuroPCR. 2015.
48. O'Neill WW, Kleiman NS, Moses J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. Circulation. 2012; 126(14): 1717–1727, doi: 10.1161/CIRCULATIONAHA.112.098194, indexed in Pubmed: 22935569.
49. Höfling B, Gonschior P, Mack B, et al. [Current status of directional coronary atherectomy in interventional cardiology]. Z Kardiol. 1991; 80 Suppl 9: 25–34, indexed in Pubmed: 1796647.
50. Umans VA, Strauss BH, Rensing BJ, et al. Comparative angiographic quantitative analysis of the immediate efficacy of coronary atherectomy with balloon angioplasty, stenting, and rotational ablation. Am Heart J. 1991; 122(3 Pt 1): 836–843, indexed in Pubmed: 1877459.
51. Mintz GS, Pichard AD, Kent KM, et al. Transcatheter device synergy: preliminary experience with adjunct directional coronary atherectomy following high-speed rotational atherectomy or excimer laser angioplasty in the treatment of coronary artery disease. Cathet Cardiovasc Diagn. 1993; Suppl 1: 37–44, indexed in Pubmed: 8324815.
52. Topol EJ. Rotablator to the rescue. Am J Cardiol. 1993; 71(10): 858–859, indexed in Pubmed: 8456767.
53. Mintz GS, Pichard AD, Popma JJ, et al. Preliminary experience with adjunct directional coronary atherectomy after high-speed rotational atherectomy in the treatment of calcific coronary artery disease. Am J Cardiol. 1993; 71(10): 799–804, indexed in Pubmed: 8456757.
54. Reifart N, Vandormael M, Krajcar M, et al. Randomized comparison of angioplasty of complex coronary lesions at a single center. Excimer Laser, Rotational Atherectomy, and Balloon Angioplasty Comparison (ERBAC) Study. Circulation. 1997; 96(1): 91–98, indexed in Pubmed: 9236422.
55. Hoffmann R, Mintz GS, Kent KM, et al. Comparative early and nine-month results of rotational atherectomy, stents, and the combination of both for calcified lesions in large coronary arteries. Am J Cardiol. 1998; 81(5): 552–557, indexed in Pubmed: 9514448.
56. Whitlow PL, Bass TA, Kipperman RM, et al. Results of the study to determine rotablator and transluminal angioplasty strategy (STRATAS). Am J Cardiol. 2001; 87(6): 699–705, indexed in Pubmed: 11249886.
57. Safian RD, Feldman T, Muller DW, et al. Coronary angioplasty and Rotablator atherectomy trial (CARAT): immediate and late results of a prospective multicenter randomized trial. Catheter Cardiovasc Interv. 2001; 53(2): 213–220, doi: 10.1002/ccd.1151, indexed in Pubmed: 11387607.
58. Khattab AA, Richardt G. Rotational atherectomy followed by drug-eluting stent implantation (Rota-DES): a rational approach for complex calcified coronary lesions. Minerva Cardioangiol. 2008; 56(1): 107–115, indexed in Pubmed: 18432173.
59. Khattab AA, Otto A, Hochadel M, et al. Drug-eluting stents versus bare metal stents following rotational atherectomy for heavily calcified coronary lesions: late angiographic and clinical follow-up results. J Interv Cardiol. 2007; 20(2): 100–106, doi: 10.1111/j.1540-8183.2007.00243.x, indexed in Pubmed: 17391217.
60. Abdel-Wahab M, Baev R, Dieker P, et al. Long-term clinical outcome of rotational atherectomy followed by drug-eluting stent implantation in complex calcified coronary lesions. Catheter Cardiovasc Interv. 2013; 81(2): 285–291, doi: 10.1002/ccd.24367, indexed in Pubmed: 22431433.
61. Abdel-Wahab M, Richardt G, Joachim Büttner H, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: the randomized ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) trial. JACC Cardiovasc Interv. 2013; 6(1): 10–19, doi: 10.1016/j.jcin.2012.07.017, indexed in Pubmed: 23266232.
62. Januszek R, Siudak Z, Dziewierz A, et al. Predictors of in-hospital effectiveness and complications of rotational atherectomy (from the ORPKI Polish National Registry 2014-2016). Catheter Cardiovasc Interv. 2017 [Epub ahead of print], doi: 10.1002/ccd.27372, indexed in Pubmed: 29068164.
63. Bartuś S, Januszek R, Legutko J, et al. Long-term effects of rotational atherectomy in patients with heavy calcified coronary artery lesions: a single-centre experience. Kardiol Pol. 2017; 75(6): 564–572, doi: 10.5603/KP.a2017.0042, indexed in Pubmed: 28631258.
64. Januszek R, Siudak Z, Dziewierz A, et al. Bailout rotational atherectomy in patients with myocardial infarction is not associated with an increased periprocedural complication rate or poorer angiographic outcomes in comparison to elective procedures (from the ORPKI Polish National Registry 2015-2016). Adv Interv Cardiol. 2018; 14(2): 135–143, doi: 10.5114/aic.2018.76404, indexed in Pubmed: 30008765.
65. Kübler P, Zimoch W, Kosowski M, et al. Acute coronary syndrome - Still a valid contraindication to perform rotational atherectomy? Early and one-year outcomes. J Cardiol. 2018; 71(4): 382–388, doi: 10.1016/j.jjcc.2017.10.012, indexed in Pubmed: 29174598.
66. Kübler P, Zimoch W, Kosowski M, et al. Novel predictors of outcome after coronary angioplasty with rotational atherectomy. Not only low ejection fraction and clinical parameters matter. Adv Interv Cardiol. 2018; 14(1): 42–51, doi: 10.5114/aic.2018.74354, indexed in Pubmed: 29743903.
67. Regulation No. 38/2017/DSOZ of the President of the Polish National Health Fund of 29 May 2017. http://www.nfz.gov.pl/zarzadzenia-prezesa/zarzadzenia-prezesa-nfz/zarzadzenie-nr-382017dsoz, 6578.html. (Accessed 31 October).
68. Legutko J. Zielone światło dla optymalizacji PCI. Kardiologia Inwazyjna. 2017; 12(1): 5–8.
69. Dudek D, Legutko J, Ochała A, et al. Association of Cardiovascular Interventions of the Polish Cardiac Society. [Guidelines of the Association of Cardiovascular Interventions of the Polish Cardiac Society for certification of coronary diagnosts and percutaneous coronary intervention operators and invasive cardiology centers in Poland]. Kardiol Pol. 2013; 71(12): 1332–1336, doi: 10.5603/KP.2013.0344, indexed in Pubmed: 24399604.

Cite this article as: Dobrzycki S, Reczuch K, Legutko J, et al. Rotational atherectomy in everyday clinical practice. Association of Cardiovascular Interventions of the Polish Society of Cardiology (*Asocjacja Interwencji Sercowo-Naczyniowych Polskiego Towarzystwa Kardiologicznego* — AISN PTK): Expert opinion. Kardiol Pol. 2018; 76(11): 1576–1584, doi: 10.5603/KP.2018.0225.